

Remarks

This application has been carefully reviewed in light of the Office Action dated September 30, 2008. Claims 1 to 3, 5 to 16, 18 to 26 and 28 to 40 are currently in the application, with claims 1 to 3, 5 to 15, 29 and 36 having been withdrawn from consideration. Claims 16 and 40 are the independent claims currently under consideration. Reconsideration and further examination are respectfully requested.

Claims 19, 24 and 35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully traverses the rejection.

Claim 19 includes the limitation that “the active ingredient continues to move or be transported after the curing stage.” The Office Action has contended that it is unclear as to where the active ingredient is moving. As recited in claim 16, a liquid incorporating one or more active ingredients is applied to a surface of a film and is absorbed within the film, either wholly or partially, to form a homogeneous polymer film product. In the Summary of the Invention on page 2 of the specification, the active ingredient is described as being transported through the surface of the film. Accordingly, Applicant respectfully submits that it would be clear to one of ordinary skill in the art that the movement or transportation of the active ingredient claimed in claim 19 is at least through the surface of the film to which the liquid incorporating the active ingredient is applied. Reconsideration and withdrawal of the § 112, second paragraph, rejection of claim 19 are respectfully requested.

Claim 24 includes the terminology “any liquid or transport medium.” The Office Action has contended that there is insufficient antecedent basis for the term “transport medium.” Page 8 of the specification describes liquids used to dissolve active ingredients acting as transport mediums for transporting the active ingredients into a film. One of ordinary skill in the art

would recognize the liquid referenced in independent claim 16 as being a transport medium, as the term is used in the specification. Accordingly, the term “transport medium” is believed to have sufficient antecedent basis in the claims. Reconsideration and withdrawal of the § 112, second paragraph, rejection of claim 24 are respectfully requested.

Claim 35 recites a “multicellular dosage form” being made from the film of claim 16. The Office Action has contended that the intended meaning of the term “multicellular dosage form” is unclear. Applicants respectfully submit that one of ordinary skill in the art would understand the meaning of “multicellular dosage form” in claim 35 as being a dosage form comprising a plurality of cavities or compartments made from the film described in claim 16. Reconsideration and withdrawal of the § 112, second paragraph, rejection of claim 35 are respectfully requested.

Claims 16, 18 to 20, 23, 24, 26, 28, 31, 35 and 40 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,552,751 (“Inaba”). Claims 25 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2003/0183643 (“Fagen”). Claims 21, 22 and 37 to 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2004/0253434 (“Patel”). Claim 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent No. 6,783,768 (“Brown”). Claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of Fagen and further in view of U.S. Patent No. 7,112,361 (“Lynn”). Applicant respectfully traverses these rejections for at least the following reasons.

Independent claim 16 is directed to a film that is produced by forming a non-gelatin polymeric film, with or without active ingredients incorporated therein, and applying a liquid

incorporating at least one active ingredient to one or more surfaces of the film. The liquid is allowed to at least partially cure and associate with the film, to result in the fluid being absorbed within the film, wholly or partially, and forming a homogeneous polymer film product. These features are not disclosed or suggested in the applied references.

Inaba concerns a multi-layered film preparation. As discussed in column 5, lines 7 to 24, Inaba prepares the multi-layered film preparation by creating multiple film-formed layers using either a drug release controlling layer solution or a drug storing layer solution. For example, Figure 1 in Inaba depicts multi-layered film preparations that consist of one or more drug storing layers sandwiched between drug release controlling layers. The Office Action has contended that the multi-layer film preparations of Inaba are identical to the homogeneous film product recited in claim 16 and therefore inherently have a homogeneous structure. Applicant respectfully disagrees.

As mentioned above, Inaba describes a process in which individual layers of the film preparation are created sequentially using either a drug release controlling layer solution or a drug storing layer solution. Inaba is not seen to disclose the resulting drug release controlling layers and the drug storing layers being made from the same materials or having the same composition. In fact, it is clear from the examples provided in Inaba that these layers have different compositions and therefore different structures. Accordingly, the multi-layer film described in Inaba is not seen to have an inherently homogenous structure, as contended in the Office Action. Furthermore, it is unclear what the basis is for the conclusion in the Office Action that the multi-layer film described in Inaba is identical to the homogeneous polymer film product of claim 16.

The other references applied in the rejections of various dependent claims are not seen to remedy the foregoing deficiencies of Inaba. Therefore, independent claim 16 is believed to be allowable over the applied references. Reconsideration and withdrawal of the § 102(b) rejection of claim 16 are respectfully requested.

Independent claim 40 is directed to a non-gelatin polymeric film that includes two or more bands with at least one active ingredient being dispersed within a particular band. The film is a single film with structural homogeneity between the bands.

As discussed above with respect to independent claim 16, Inaba describes a multi-layer film preparation that includes drug release controlling layers and drug storing layers, each having layer a different composition and structure. Accordingly, Inaba is not seen to disclose or suggest a non-gelatin polymeric film that includes two or more bands with at least one active ingredient dispersed within a particular band, where the film is a single film with structural homogeneity between the bands.

The other references applied in the rejections of various dependent claims are not seen to remedy the foregoing deficiencies of Inaba. Therefore, independent claim 40 is believed to be allowable over the applied references. Reconsideration and withdrawal of the § 102(b) rejection of claim 40 are respectfully requested.

The remaining claims current under consideration are dependent, either directly or indirectly, from independent claim 16 discussed above and therefore are believed to be allowable over the applied references for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, however, the individual consideration of each on its own merits is respectfully requested.

In view of the foregoing remarks, the claims currently under consideration are believed to be in condition for allowance and such action is respectfully requested at the Examiner's earliest convenience.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203 and please credit any excess fees to such deposit account.

Respectfully submitted,

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